K091043

TRANSMOTION MEDICAL INC

MAY 11 2009

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

TransMotion Medical, Inc.
1441 Wolf Creek Trail
Sharon Center, Ohio 44274
Phone: (866) 860-8447
Fax: (330) 239-4465

Contact Person: Ralph Rogers
General Manager
TransMotion Medical, Inc.

Date Prepared: April 5, 2009

Name of Device

TMM6 Power Drive Chair

Common or Usual Name

Stretcher

Classification Name

Powered Wheeled Stretcher

Predicate Device

Stryker Powered Wheeled Stretcher (K022309)

Intended Use

The TransMotion Medical Model TMM6 Power Drive Chair is intended to provide a method of transporting patients within health care facilities

Device Description

The TransMotion Medical, Inc. TMM6 Power Drive Chair (TMM6) is a battery powered device designed for use in short term (≤ 23 hours) patient care facilities. Its intended

function and use is to transport patients within the confines of the facility, where patient care is being administered. It can also be used to support the patient during examinations, physical therapy and other clinical activity which may take place in the facility.

The TMM6 is unique in that it can support and transport patients in either a supine (laying) position or seated position (See Figures 1 and 2 below). This enhances patient access by caregivers and also provides for greater patient comfort.

Substantial Equivalence

The TransMotion Medical, Inc. TMM6 Power Drive Chair is substantially equivalent to other devices of comparable type that are currently being legally marketed within the United States. Specifically, the is substantially equivalent to the Stryker Powered Wheel Stretcher ***(K022309).***

Performance Data

The TMM6 Power Drive Chair will comply with the following voluntary standards;

IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety 1: Safety Requirements for Medical Electrical Systems
IEC 60601-1-2	Medical Electrical Equipment – Part 1: General Requirements for Safety 2: Electromagnetic Compatibility – Requirements and Tests

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2009

TransMotion Medical, Inc.
% Mr. Ralph Rogers
General Manager
1441 Wolf Creek Trail
Sharon Center, Ohio 44274

Re: K091043
Trade Name: TransMotion Medical, Inc. Model TMM6 Power Drive Chair
Regulation Number: 21 CFR 890.3690
Regulation Names: Powered wheeled stretcher
Regulatory Class: II
Product Code: INK
Dated: April 6, 2009
Received: April 13, 2009

Dear Mr. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

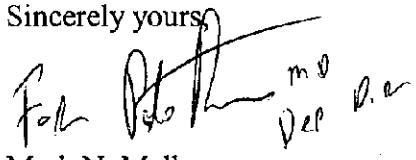
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: TransMotion Medical, Inc. Model TMM6 Power Drive Chair

Indications for Use:

The TransMotion Medical TMM6 Power Drive Chair is designed for use in short term (≤ 23 hours) health care facilities. Its' intended use is to provide a method of transporting patients within the facility.

Prescription Use ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

X(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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